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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,588	08/31/2001	Nobuko Yamamoto	35.C15717	9425

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EXAMINER

SIEW, JEFFREY

ART UNIT                      PAPER NUMBER

1637

DATE MAILED: 09/10/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

Applicant(s)

09/942,588

YAMAMOTO ET AL.

Examiner

Art Unit

Jeffrey Siew

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 07 June 2002.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-23 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a)  All    b)  Some \*    c)  None of:
1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other:

### DETAILED ACTION

1. The response filed 6/7/02 has been fully considered and deemed persuasive in part. The response's argument regarding the Cronin et al reference is not found persuasive. The response argues that Cronin et al teaches determining luminescence at the location of each immobilized array and would require a precision detection apparatus. The response is reminded that examination of claims does not expressly state any negative limitation of not using a precision detection apparatus. Claims are read as reasonably as possible and while response's claim of the preferred embodiment of the invention may be encompassed by the claims so too are Cronin et al's device and method. Moreover, Cronin teaches a variety of tiling and pooling strategies. The response states that ".e.g the probes are grouped by regions for example the number of mismatches .." The claims are read broadly and regions are to contain but are not necessarily limited to specific types of probes. The claimed regions would still read on Cronin et al's tiling and pooling strategies. The art rejection over Cronin et al are therefore maintained.

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in-
  - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

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(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1,2,5-16 & 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Cronin et al (US6,309,823 Oct. 30, 2001).

Cronin et al teach a array and method to detect mutations using the array in which multiple different regions correspond to different probe sets that are complementary to reference sequence and mismatch sequences (see whole doc. esp. abstract). They teach that the probes may be of various lengths e.g. 15 base pairs (see col. 11 lines 17-25). They teach that variation of interrogation position of probes may be detected by comparing presence of mutation of single mismatch probe with a double mismatch probes (see col.12 lines 29-45). The probes are each arranged in column orders corresponding to the A,C,G,T lanes (see col. 13 lines 54-65). They also teach that the hybridization of target and reference may be performed sequentially and the analyzed by comparing the signals of the target sequence with the reference to determine the variation (see col. 17 lines 10-45 & col. 14 lines 20-39). The array are immobilized by cell or different regions and include a blank cell (see col. 22 lines 6-18) and also multiplex tiling with perfect match probes, and three other probes which show single base mismatches (see col.20 lines 16-20).They teach a system for detecting the chip (see figure 21).

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 17 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cronin et al (US6,309,823 Oct. 30, 2001) in view of Drmanac (US6,309,824 oct. 20 2001).

The teachings of Cronin et al are described previously.

Cronin et al do not explicitly teach fluorescent or chemiluminescent labels.

Drmanac teach the use of fluorescent or chemiluminescent labeling in probe arrays (see col. 6 lines 15-18).

One of ordinary skill in the art would have been motivated to apply Drmanac's labeling techniques to Cronin et al's hybridization assay in order to provide for efficient and safe detection of bound hybrids. As chemiluminescent and fluorescent labels were well known and

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commonly used at the time the invention was made, it would have been prima facie obvious to apply Drmanac's teachings in order to successfully and efficiently detect hybridized targets in Cronin et al's assay.

### SUMMARY

5. No claims allowed.

#### *Conclusion*

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and

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whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Monica Graves for Art Unit 1637 whose telephone number is (703)-306-2938.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

  
**JEFFREY SIEW**  
**PRIMARY EXAMINER**

August 18, 2002